May 20, 2021

DePuy Ireland UC
% Erin Combs
Senior Regulatory Affairs Specialist
Depuy Orthopaedics, Inc
700 Orthopaedic Drive
Warsaw, Indiana 46582

Re: K210581
Trade/Device Name: Actis DuoFix Hip Prosthesis- Collarless
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: MEH, LPH, KWL, KWY
Dated: April 30, 2021
Received: May 3, 2021

Dear Erin Combs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William Jung, Ph.D.
Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210581

Device Name
Actis DuoFix Hip Prosthesis - Collarless

Indications for Use *(Describe)*

INDICATIONS FOR USE

Total hip replacement or hip arthroplasty is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Certain cases of ankylosis.

Hemi-hip arthroplasty is indicated in the following conditions:

1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
3. Avascular necrosis of the femoral head.
4. Non-union of femoral neck fractures.
5. Certain high subcapital and femoral neck fractures in the elderly.
6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

The ACTIS™ DUOFIX™ Hip Prosthesis – Collarless is indicated for cementless use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

(As required by 21 CFR 807.92 and 21 CFR 807.93)

Submitter Information	
Name	DePuy Ireland UC
Address	Loughbeg, Ringaskiddy Co. Cork, IRELAND
Establishment Registration Number	3015516266
Name of contact person	Elaine Pears
e-mail address	epears@its.jnj.com and DePuySynthesJointsRegulatoryAffairs@its.jnj.com
Alternative contact person	Clare Hill
e-mail address	chill7@its.jnj.com
Work mobile	+44 7795 389956 (UK time zone)
Date prepared	16th February 2021
Name of device	
Trade or proprietary name	DePuy Actis DuoFix Hip Prosthesis – Collarless
Common or usual name	Uncemented Hip Prosthesis
Classification name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis; Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.
Class	II
Classification panel	87 Orthopedics
Regulation	21 CFR 888.3358; 888.3353; 888.3360; 888.3390
Product Code(s)	MEH, LPH, KWL, KWY
Legally marketed device(s) to which equivalence is claimed	Primary predicate - DePuy Actis DuoFix Hip Prosthesis K160907, cleared July 19, 2016 Secondary predicate - DePuy Summit DuoFix Hip Prosthesis K170339, cleared April 26, 2018 Reference predicate for hydroxyapatite (HA) coating process step – DePuy Actis DuoFix Hip Prosthesis K202472, cleared October 21, 2020
Reason for 510(k) submission	The purpose of this 510K submission is to obtain market clearance for DePuy Actis DuoFix Hip Prosthesis – Collarless.

Device description	The DePuy Actis DuoFix Hip Prosthesis – Collarless is a forged titanium (Ti-6Al-4V) femoral stem designed to be used as one component of a system of prostheses in hip arthroplasty. The stems are compatible with both unipolar and bipolar femoral heads intended for hemi-hip arthroplasty and with modular metal and ceramic femoral heads intended for total hip arthroplasty The Actis DuoFix Hip Prosthesis – Collarless implants have sintered commercially pure titanium bead porous coating (Porocoat®) and a thin layer of plasma-sprayed hydroxyapatite (HA) coating. The stem consists of a wide range of stem neck designs and sizes allowing an accurate anatomical match for each patient. The Actis DuoFix Hip Prosthesis – Collarless is designed as a line extension to the primary predicate Actis DuoFix Hip Prosthesis (K160907) to meet the need of surgeons whose preference is to use a femoral stem without a collar for hip arthroplasty.
Intended use of the device	Total hip arthroplasty and hemi-hip arthroplasty
Indications for use	Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Certain cases of ankylosis. Hemi-hip arthroplasty is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICES			
Characteristics	**Subject Device: DePuy Actis DuoFix Hip Prosthesis - Collarless**	**Primary Predicate Device: DePuy Actis DuoFix Hip Prosthesis K160907**	**Secondary Predicate Device: DePuy Summit DuoFix Hip Prosthesis K170339**
Intended Use and Indications for Use	Same as primary predicate	Intended for use in total hip arthroplasty and hemi-hip arthroplasty. Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Certain cases of ankylosis. Hemi-hip arthroplasty is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.	Intended for use in total hip arthroplasty and hemi-hip arthroplasty. Total hip replacement is indicated in the following conditions: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head or neck. 4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement. 5. Certain cases of ankylosis. Hemi-hip replacement is indicated in the following conditions: 1. Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation. 2. Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation. 3. Avascular necrosis of the femoral head. 4. Non-union of femoral neck fractures. 5. Certain high subcapital and femoral neck fractures in the elderly. 6. Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement. 7. Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

Material	Same as primary predicate	**Femoral stem**: Wrought titanium alloy **Porous coating**: Commercially pure unalloyed Titanium sintered bead porous coating (Porocoat®) **HA coating**: Hydroxyapatite powder	Same as primary predicate
Fixation	Same as primary predicate	Uncemented	Same as primary predicate
Stem Size	Same as primary predicate	0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1, 2, 3, 4, 5, 6, 7, 8, 9, 10
Neck Offset	Same as primary predicate	Standard, High	Same as primary predicate
Collar	Same as secondary predicate	Collared	Collarless
Sterile Method	Same as primary predicate	Gamma irradiation	Same as primary predicate
SAL	Same as primary predicate	10^{-6}	Same as primary predicate
Packaging	Same as primary predicate	Double PETG blister with Tyvek peel lid	Same as primary predicate
Shelf Life	Same as primary predicate	10 years	Same as primary predicate

The subject device [Actis DuoFix Hip Prosthesis – Collarless] is identical in design to the primary predicate device [Actis DuoFix Hip Prosthesis (K160907)] with the single exception that, in common with the secondary predicate [Summit DuoFix Hip Prosthesis (K170339)], there is no collar on the neck of the device.

The subject device has the same intended use as both the primary and secondary predicate devices. The subject and both predicate devices are made from the same materials and have the same method of fixation (cementless). Method of sterilization, Sterility Assurance Level (SAL), packaging materials and shelf-life are the same across the subject and predicate devices.

Indications for use and range of stem sizes and neck offsets available are identical for the subject device and the primary predicate.

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Distal fatigue testing (to ISO 7206-4: 2010), neck fatigue testing (to ISO 7206-6:2013) and biocompatibility evaluation (to ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-10:2010, ISO 10993-11:2017 and ISO 10993-18:2020) were carried out as part of design verification for the devices in order to demonstrate substantial equivalence of safety and efficacy with the predicate devices.

Magnetic Resonance Imaging safety evaluation testing was performed using ASTM F2503-13, and the tests evaluated the worst-case components and constructs for magnetically induced force (ASTM F2052-15), torque (ASTM F2213-17), image artefact (ASTM 2119-07) and RF heating (ASTM F2182-11a). The testing concluded that there are no safety issues related to magnetic field interactions under specific conditions identified in the labelling.

The proposed devices also meet the requirement of bacterial endotoxin testing as specified in ANSI/AAMI ST 72:2019.

Hydroxyapatite characterization data, as recommended in the FDA Guidance *510(k) Information needed for Hydroxyapatite coated Orthopedic Implants*, is provided.

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The subject DePuy Actis DuoFix Hip Prosthesis - Collarless devices are substantially equivalent to the predicate DePuy Actis DuoFix and DePuy Summit DuoFix hip prostheses (K160907 and K170339).